



DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

[Docket No. PTO-P-2014-0065]

Grant of Interim Extension of the Term of U.S. Patent No. 5,693,323;

Recombinant Humanized Monoclonal Antibody (IgG₁, Kappa)-Mepolizumab

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice of Interim Patent Term Extension.

SUMMARY: The United States Patent and Trademark Office has issued an order granting interim extension under 35 U.S.C. 156(d)(5) for a one-year interim extension of the term of U.S. Patent No. 5,693,323.

FOR FURTHER INFORMATION CONTACT: Mary C. Till by telephone at (571) 272-7755; by mail marked to her attention and addressed to the Commissioner for Patents, Mail Stop Hatch-Waxman PTE, P.O. Box 1450, Alexandria, VA 22313-1450; by fax marked to her attention at (571) 273-7755; or by e-mail to Mary.Till@uspto.gov.

SUPPLEMENTARY INFORMATION: Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review, and that the patent may be extended for interim periods of up to one year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On November 24, 2014, GlaxoSmithKline LLC and SmithKline Beecham Limited timely filed an application under 35 U.S.C. 156(d)(5) for an interim extension of the term of U.S. Patent No. 5,693,323. The patent claims the human biological product Mepolizumab, a recombinant humanized monoclonal antibody (IgG1, Kappa). The application indicates that a Biologics License Application, BLA 125526, for the human biological product has been filed, and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. 156, and that the patent should be extended for one year as required by 35 U.S.C. 156(d)(5)(B). Because it is apparent that the regulatory review period will continue beyond the original expiration date of the patent, December 23, 2014, interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 5,693,323 is granted for a period of one year from the original expiration date of the patent.

Dated: December 5, 2014.

Andrew Hirshfeld,
Deputy Commissioner for Patent Examination Policy,
United States Patent and Trademark Office.

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